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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/831,804	07/23/2001	Florence Bordon-Pallier	146.1365	9488

7590 08/28/2002

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EXAMINER
MCKELVEY, TERRY ALAN

ART UNIT	PAPER NUMBER
1636	

DATE MAILED: 08/28/2002

8

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/831,804	BORDON-PALLIER ET AL.	
	Examiner	Art Unit	
	Terry Mckelvey	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondenc address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19,22,24,25 and 27-29* is/are pending in the application.

4a) Of the above claim(s) *12,19,22,24,25,28,29* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11,13-18 and 27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claims 1-11, 13-18, and 27, drawn to isolated polynucleotide, process for preparation of a recombinant protein (first method of using the polynucleotide), expression vector, host cell, and kit(only in so far as it is drawn to the polynucleotide).

Group II, claims 12, 24, and 27, drawn to polypeptide, method of inducing an immunological response (first method of using the polypeptide), and kit (only in so far as it is drawn to the polypeptide).

Group III, claim 19, drawn to process of screening antifungal products (second method of using the polypeptide).

Group IV, claim 22, drawn to pharmaceutical composition containing inhibitor.

Group V, claims 25 and 27, drawn to antibody and kit (only in so far as it is drawn to antibody).

Group VI, claim 28, drawn to method of treating fungal infections.

Group VII, claim 29, drawn to method of treating diseases (third method of using the polypeptide).

The inventions listed as Groups I-VII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: PCT Rule 13.2 requires that unity of invention exists only when there is a shared same or corresponding technical feature among the claimed inventions. Each of Groups I-VII have a special technical feature not shared by the remaining groups (or are drawn to subsequent methods of use). Group I is directed to the polynucleotide and first method of using the polynucleotide. Group II is drawn to a polypeptide and first method of using the polypeptide. Group III is drawn to a process of screening which is the second method of using the polypeptide. Group IV is drawn to a pharmaceutical composition containing an inhibitor. Group V is drawn to an antibody. Group VI is drawn to the use of a product not used in the other groups. Group VII is drawn to a third method of using the polypeptide.

During a telephone conversation with Charles Muserlian on 7/2/02 a provisional election was made with traverse to prosecute the invention of Group I, claims 1-11, 13-18, and 27. Affirmation of this election must be made by applicant in replying to this Office action. Claims 12, 19, 22, 24-25, and 28-29 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must

be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-3, 5, 8-11, 13-17, and 27 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to isolated polynucleotide containing a polynucleotide having at least 50% similarity with a polynucleotide coding for a polypeptide with the transcription factor function and having an amino acid sequence homologous (defined as at least 40% homology) with SEQ ID NO:3. They are also drawn to DNA sequences which "is that of the CatfIIIA gene coding for a protein having the biological function of

transcription factor of Candida albicans CATFIIIA containing the nucleotide sequence SEQ ID NO:1". A process, host cell, and kit drawn to the polynucleotides are also claimed. The polynucleotides and DNA sequences are limited to those that encode a polypeptide that has the biological function (transcription function) of SEQ ID NO:3. The product and method claims are genus claims because they comprise the use of two different products each of which constitutes a genus: the polynucleotide and DNA sequences are drawn to a broad range of nucleic acids, related by homology not only according to the nucleic acid sequence, but also additional homology to even more distantly related sequences according to protein homology. Thus, the claimed polynucleotides and DNA sequences encompass many different nucleic acid sequences having one or more nucleotide substitutions, deletions, insertions, and/or additions to the polynucleotide set forth by the application: encoding SEQ ID NO:3, limited to those nucleic acids that encode a polypeptide that has the transcription function of SEQ ID NO:3.

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of

complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. In this case, the only factors present in the claims are a partial structure in the form of percent identity, further limited by a functional limitation drawn to transcriptional activity. Beyond the specific description of one protein, which is one C. albicans TFIIIA protein sequence, SEQ ID NO:3, a general description of conserved zinc fingers and serine-rich region (which covers most of the sequence), there is little identification in the specification of all of the particular portions of the structure that must be conserved for the claimed activity. Accordingly, in the absence of sufficient recitation of all of the distinguishing characteristics needed for function, the specification does not provide adequate written description of the claimed genus.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed*." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or

she] invented what is claimed." (See *Vas-Cath* at page 1116). As discussed above, the skilled artisan cannot envision the detailed chemical structure of the encompassed genus of polynucleotides, and therefore conception is not achieved until reduction of practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is required. See *Fiers v. Ravel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGFs were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence.

Therefore, only isolated polynucleotides encoding the polypeptide set forth as SEQ ID NO:3, but not the full breadth of the claims, meets the written description provision of 35 USC 112, first paragraph. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 USC 112, first paragraph is severable from its enablement provision (see page 1115).

Claim 18 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention.

The application discloses and claim 18 claims plasmid deposited at the CNCM under the number I-2072 that is encompassed by the definitions for **biological material** set forth in 37 C.F.R. § 1.801. Because it is apparent that this biological material is essential for practicing the claimed invention, it must be obtainable by a reproducible method set forth in the specification or otherwise be known and readily available to the public as detailed in 37 C.F.R. §§ 1.801 through 1.809.

It is unclear whether this biological material is known and readily available to the public or that the written instructions are sufficient to reproducibly construct this biological material from starting materials known and readily available to the public. Accordingly, availability of such biological material is deemed necessary to satisfy the enablement provisions of 35 U.S.C. § 112. If this biological material is not obtainable or available, the requirements of 35 U.S.C. § 112

may be satisfied by a deposit of the biological material. In order for a deposit to meet all criteria set forth in 37 C.F.R. §§ 1.801-1.809, applicants or assignee must provide assurance of compliance with provisions of 37 C.F.R. §§ 1.801-1.809, in the form of a declaration or applicant's representative must provide a statement. The content of such a declaration or statement is suggested by the enclosed attachment. Because such deposit will not have been made prior to the effective filing date of the instant application, applicant is required to submit a verified statement from a person in a position to corroborate the fact, which states that the biological material which has been deposited is the biological material specifically identified in the application as filed (37 C.F.R. § 1.804). Such a statement need not be verified if the person is an agent or attorney registered to practice before the Office. Applicant is also reminded that the specification must contain reference to the deposit, including deposit (accession) number, date of deposit, name and address of the depository, and the complete taxonomic description.

In the instant case, it appears that the biological material has been deposited at CNCM. It is unclear whether it has been deposited according to the Budapest Treaty. The complete reference to the deposit is missing from the

specification, as is the required statement concerning the deposit. Full compliance with the biological deposit rules would obviate the instant rejection.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-11, 13-18, and 27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claims 1, 2, etc, the use of "Isolated polynucleotide" or "Polynucleotide", etc, without the use of a proper (indefinite) article ("A") renders the claims vague and indefinite because the claims do not form a proper complete sentence as required. (The claims should start in, in the header, the first part of the sentence, such as "We claim:". Amending the claims to add the proper articles would be remedial.

Regarding claim 1, etc, the use of "or at least", and "preferably at least", renders the claims vague and indefinite for the following reason. A broad range or limitation together

with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949).

Regarding claim 1, etc, the use of "with the transcription factor function" renders the claims vague and indefinite because it is unclear whether the transcription factor function of the amino acid sequence of SEQ ID NO:3 is intended, or any transcription factor function is intended. For examination purpose, it appeared that the former was intended. Amending the claims to clarify the metes and bounds of the transcription factor function intended would be remedial.

Regarding claim 1, etc, the use of "the polynucleotide defined in a) and b)" renders the claims vague and indefinite because it is unclear whether only those polynucleotides that meet both a) and b) limitations are intended (essentially no polynucleotides) or either a) or b) polynucleotides (which appears to be intended). Amending the claims to replace "and" between a) and b) with "or" would be remedial.

Regarding claim 5, etc, there is no positive antecedent basis for "DNA sequence as defined in claim 1".

Regarding claim 5, etc, the use of "this DNA sequence is that of the CAtfIIIA gene coding for a protein having the biological function of transcription factor of Candida albicans CATFIIIA containing the nucleotide sequence SEQ ID NO:1" renders the claims vague and indefinite for the following reasons. It is unclear how a protein having the biological function of C. albicans CATFIIIA (a protein) can contain a nucleotide sequence of SEQ ID NO:1. The metes and bounds of what constitutes a "CAtfIIIA gene" as claimed is also unclear rendering the claim vague and indefinite. It is entirely unclear how this claim is intended to further limit the isolated polynucleotide of claim 1.

Regarding claim 7, etc, there is no positive antecedent basis for "DNA sequence of the CAtfIIIA gene according to claim

5" because claim 5 recites "DNA sequence" without the "of the CAtfIIIA gene" portion. Also, it should be noted that because of the lack of clarity of claim 5, it is unclear whether this claim further limits claim 5. If claim 5 is intended to be limited in some way to SEQ ID NO:1, then this claim does not further limit claim 5 because SEQ ID NO:1 inherently encodes SEQ ID NO:3. Also, it is unclear what is intended by "(412 AA)" because SEQ ID NO:3 is a 412 amino acid sequence and thus it is redundant and unclear to include "(412 AA)" because it falsely implies that SEQ ID NO:3 can be less than 412 aa.

Regarding claim 8, etc, the use of "DNA sequence coding for the transcription factor CATFIIIA according to claim 5" lacks positive antecedent basis for the same reason as above for claim 7.

Regarding claim 8, etc, the use of "as well as" renders the claims vague and indefinite because it is unclear whether what follows is intended to be a further limitation of the preamble DNA sequence, or whether what follows are alternative DNA sequences. If the former is intended, then the phrase "as well as" needs to be deleted and the following phrases written to modify the DNA sequence recited in the preamble. If the latter it intended, then the claims need to be rewritten in a Markush

format based upon the preamble, which further limits the preamble DNA sequence.

Regarding claim 8, etc, the use of "DNA sequences which hybridize with it and/or have a significant homology with this sequence or fragments of it and having the same function" renders the claims vague and indefinite because it is unclear what "it" is in each case, it is unclear to further limit the preamble DNA sequence by limiting the DNA sequence with those that hybridize with it (they are different DNA sequences, not a proper limitation, assuming that this is what was intended), the metes and bounds of what constitutes "significant homology" in this context are unclear, and it is unclear what constitutes having the same function (and it is unclear which of the alternatives the function applies to).

Regarding claim 9, etc, the use of "at least one nucleotide coding for a protein having the same biological activity" renders the claims vague and indefinite because it is unclear how a nucleotide by itself can code for a protein having the activity as claimed.

Regarding claim 9, etc, the use of "modifications introduced by suppression" renders the claims vague and indefinite because suppression mutations in this context (in the absence of any other sequences) is unclear. It appears that

"deletion" instead of "suppression" was intended and thus replacing "suppression" with "deletion" would be remedial.

Regarding claim 11, etc, the use of "a protein with a similar function the AA sequence of which has a homology ... with the AA sequence coded by said DNA sequence" renders the claims vague and indefinite because the metes and bounds of what constitutes "similar function" are unclear and it is unclear which DNA sequence is referred to by "said DNA sequence" within the context of what amino acid sequence the homology is compared to. Also, it should be noted that abbreviations for common words should not be used because lack of clarity could result. Abbreviations which are defined should be reserved for unique terms.

Regarding claim 13, the use of "the said recombinant protein" renders the claims vague and indefinite because of the redundant use of both "said" and "the". Also, what constitutes an "appropriate host" is unclear. Finally, because the DNA sequence according to claim 5 does not appear to be limited to encoding only protein having the amino acid sequence of SEQ ID NO:3, it is unclear how expression of this DNA sequence results in (only) CATFIII (which misses the "A") having the amino acid sequence of SEQ ID NO:3.

Regarding claim 27, the use of "a sequence having a similar function or functional fragment of this sequence" renders the claim vague and indefinite because the metes and bounds of similar function and functional fragment are unclear because it is unclear what the function is and how it can be similar. Also, the use of "the polypeptide coded by this sequence or a polypeptide fragment having the same function or an antibody directed against such a polypeptide coded by this DNA sequence or against a fragment of this polypeptide" renders the claim vague and indefinite because it is unclear whether this extremely confusing phrase is intended to somehow modify the DNA sequence recited earlier in the claim, or whether it is intended that these are alternative components of the kit. The latter appears to be intended, hence the restriction putting these very different kits (drawn to the very different components) into multiple, different groups. This part of the claim should be deleted to remove the non-elected subject matter.

The phrasing and format of the claims are very unclear for the reasons set forth above. Every attempt was made to identify all specific parts of the claims that render the claims vague and indefinite. Some of those problems are in multiple claims and thus must be corrected in all of the affected claims, even

those not specifically identified. However, because of the extreme nature of the problems with the claims (probably due to translation from a foreign language), it is possible some problems are masked by other problems, and thus could not be clearly identified.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 5, 8-11, 14, and 27 are rejected under 35 U.S.C. 102(b) as being anticipated by Archambault et al (applicant supplied reference).

Archambault et al teach an isolated polynucleotide which encodes S. cerevisiae TFIIIA which encodes an amino acid sequence which comprises more than five consecutive amino acids identical to SEQ ID NO:3. See the attached sequence comparison. Therefore, the polynucleotide taught by the reference comprises a polynucleotide that has at least 15 consecutive bases which encodes part of SEQ ID NO:3 at 100% homology (let alone the

claim being drawn to as low as 50% homology for the nucleic acid sequence and as low as 40% homology for the protein sequence, which would result in longer matches at the lower homologies). The polynucleotide being DNA and RNA (made during the in vitro synthesis of the protein, page 3283, column 2) are taught. The DNA encodes S. cerevisiae TFIIIA which because it is a TFIIIA protein, has the biological function of CATFIIIA. Because of the degree of sequence similarity, the nucleic acid sequence taught by the reference has significant homology with the claimed nucleic acids, would hybridize under certain conditions to the nucleic acids, and has the same function (TFIIIA function). The differences in the nucleic acid taught by the reference versus the claimed nucleic acids can be considered to be comprising modifications introduced by insertion, deletion, and/or substitution. An expression vector containing the polynucleotide is taught (page 3283, column 1).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at

> the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-3, 5, 8-11, 13-17, and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Archambault et al (applicant supplied reference) in view of Fujiwara et al (U.S. patent No. 5,808,030).

Archambault et al teach an isolated polynucleotide which encodes S. cerevisiae TFIIIA which encodes an amino acid sequence which comprises more than five consecutive amino acids identical to SEQ ID NO:3. See the attached sequence comparison. Therefore, the polynucleotide taught by the reference comprises a polynucleotide that has at least 15 consecutive bases which

encodes part of SEQ ID NO:3 at 100% homology (let alone the claim being drawn to as low as 50% homology for the nucleic acid sequence and as low as 40% homology for the protein sequence, which would result in longer matches at the lower homologies). The polynucleotide being DNA and RNA (made during the in vitro synthesis of the protein, page 3283, column 2) are taught. The DNA encodes S. cerevisiae TFIIIA which because it is a TFIIIA protein, has the biological function of CATFIIIA. Because of the degree of sequence similarity, the nucleic acid sequence taught by the reference has significant homology with the claimed nucleic acids, would hybridize under certain conditions to the nucleic acids, and has the same function (TFIIIA function). The differences in the nucleic acid taught by the reference versus the claimed nucleic acids can be considered to be comprising modifications introduced by insertion, deletion, and/or substitution. An expression vector containing the polynucleotide is taught (page 3283, column 1). Archambault et al teach use of expressed TFIIIA in performing functional analysis (throughout the reference).

Archambault et al do not specifically teach expression of the DNA sequence according to claim 5 in a host followed by isolation and purification of the protein. This reference also does not specifically teach host cells transformed with the

vector, the host being DH5 alpha E. coli or XL1-Blue E. coli, and the process of production of the protein in which the host cell is S. cerevisiae.

Fujiwara et al teach transformation of host cells such as S. cerevisiae or E. coli cells with expression vectors comprising a nucleic acid encoding a TFIIIA gene, followed by expression, isolation, and purification of the protein (columns 4-5). This reference teaches that various other strains of organisms that are known in the art and other vectors, may be used for expression (column 5).

It would have been obvious to one of ordinary skill in the art at the time of the invention to use the methods taught by Fujiwara et al concerning production of TFIIIA to produce purified TFIIIA from the gene and constructs taught by Archambault et al because Fujiwara et al teach that it is within the ordinary skill in the art to produce large amounts of purified TFIIIA using the methods taught by the reference and Archambault et al teach a different TFIIIA protein that is used in analysis of function.

One would have been motivated to do so for the expected benefit of producing large amounts of purified TFIIIA protein for use in the analysis taught by taught by Archambault et al. Based upon the teachings of the cited references and absent any

evidence to the contrary, there would have been a reasonable expectation of success to make the purified TFIIIA protein taught by Archambault et al using the method taught by Fujiwara et al.

It should be noted that the instant rejections are based upon the examiner's best interpretation of what was intended to be claimed for each claim. Because of the extensive and greatly overlapping problems with the clarity of the claims, it is possible that the examiner's interpretation of what was intended to be claimed is sometimes incorrect and thus the intended claim limitations are different from the examiner's interpretation.

Conclusion

No claims are allowed.

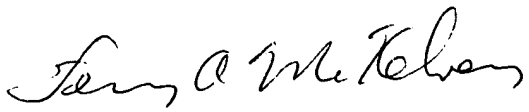
Certain papers related to this application may be submitted to Art Unit 1636 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). The official fax telephone numbers for the Group are (703) 308-4242 and (703) 305-3014. NOTE: If Applicant does submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning missing attachments or other minor formalities of this communication should be directed to the patent analyst, Zeta Adams, whose telephone number is (703) 305-3291.

Any inquiry concerning rejections or other major issues in this communication or earlier communications from the examiner should be directed to Terry A. McKelvey whose telephone number is (703) 305-7213. The examiner can normally be reached on Monday through Friday, except for Wednesdays, from about 7:30 AM to about 6:00 PM. A phone message left at this number will be responded to as soon as possible (i.e., shortly after the examiner returns to his office).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Remy Yucel, can be reached at (703) 305-1998.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.



Terry A. McKelvey, Ph.D.
Primary Examiner
Art Unit 1636

August 26, 2002

SUGGESTION FOR DEPOSIT OF BIOLOGICAL MATERIAL ATTACHMENT

A declaration by applicant or assignee, or a statement by applicant's agent identifying a deposit of biological material and averring the following may be sufficient to overcome an objection or rejection based on a lack of availability of biological material. Such a declaration:

1. Identifies declarant.

2. States that a deposit of the material has been made in a depository affording permanence of the deposit and ready accessibility thereto by the public if a patent is granted. The depository is to be identified by name and address. (See 37 C.F.R. § 1.803).

3. States that the deposited material has been accorded a specific (recited) accession number.

4. States that all restrictions on the availability to the public of the material so deposited will be irrevocably removed upon the granting of the patent. (See 37 C.F.R. § 1.808(a)(2)).

5. States that the material has been deposited under conditions that assure that access to the material will be available during the pendency of the patent application to one determined by the Commissioner to be entitled thereto under 37 C.F.R. § 1.14 and 35 U.S.C. § 122. (See 37 C.F.R. § 1.808(a)(1)).

6. States that the deposited material will be maintained with all the care necessary to keep it viable and uncontaminated for a period of at least five years after the most recent request for the furnishing of a sample of the deposited microorganism, and in any case, for a period of at least thirty (30) years after the date of deposit or for the enforceable life of the patent, whichever period is longer. See 37 C.F.R. § 1.806).

7. That he/she declares further that all statements made therein of his/her own knowledge are true and that all statements made on information and belief are believed to be true; and further, that these statements were made with knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the instant patent application or any patent issuing thereon.

Alternatively, it may be averred that deposited material has been accepted for deposit under the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure (e.g., see 961 OG 21, 1977) and that all restrictions on the availability to the public of the material so deposited will be irrevocably removed upon the granting of a patent.

Additionally, the deposit must be referred to in the body of the specification and be identified by deposit (accession) number, date of deposit, name and address of the depository, and the complete taxonomic description.